



Department of Justice

Acting United States Attorney Michael K. Loucks
District of Massachusetts

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WWW.USDOJ.GOV/USAO/MA

CONTACT: CHRISTINA DiIORIO-STERLING
PHONE: (617)748-3356
E-MAIL: USAMA.MEDIA@USDOJ.GOV

STRYKER BIOTECH AND ITS TOP MANAGEMENT INDICTED FOR ILLEGAL PROMOTION OF MEDICAL DEVICES USED IN INVASIVE SURGERIES

BOSTON, MA - Stryker Biotech, LLC, a corporation based in Hopkinton, Massachusetts, and its former president, Mark Philip of Lexington, Massachusetts, and its current sales managers, William Heppner of Illinois, David Ard of California, and Jeff Whitaker of North Carolina, were charged today in federal court with participating in a fraudulent marketing scheme of medical devices used during invasive spinal and long bone surgeries. Stryker Biotech and Mark Philip were also charged with making false statements to the United States Food and Drug Administration ("FDA").

Acting United States Attorney Michael K. Loucks; Mark Dragonetti, Resident Agent in Charge of the Food & Drug Administration - Office of Criminal Investigations; Susan J. Waddell, Special Agent in Charge of Health and Human Services, Office of the Inspector General - Office of Investigations; and Warren T. Bamford, Special Agent in Charge of the Federal Bureau of Investigation - Boston Field Division, announced today that **STRYKER BIOTECH, LLC, MARK PHILIP, WILLIAM HEPPNER, DAVID ARD** and **JEFF WHITAKER** were charged in an Indictment with five counts of wire fraud and one count of conspiracy. **STRYKER BIOTECH, DAVID ARD** and **JEFF WHITAKER** were also charged with misbranding. In addition, **STRYKER BIOTECH** and **MARK PHILIP** were charged with making false statements to the FDA.

The Indictment alleges that all of the defendants participated in an illegal marketing scheme to promote medical devices used during invasive surgeries, and in doing so having defrauded medical professionals and the FDA. In particular, the defendants are alleged to have promoted devices known as OP-1 Implant and OP-1 Putty. These devices were used to stimulate bone growth in long bones and the spine. These devices were approved by the FDA only pursuant to a highly restrictive Humanitarian Device Exemption ("HDE"). One of the restrictions was that the device could only treat a condition that affected fewer than 4,000 patients in the United States, and could not be sold for a profit. The Indictment charges that the defendants promoted the use of these devices in a manner that was different from its FDA approved use; namely they promoted a combination of the devices with a bone void filler, called Calstrux, and in furtherance of that promotion provided "recipes" to surgeons, medical technicians and others as to how to mix the OP-1 products with Calstrux. It is alleged that some of these untested "recipes" called for medical personnel to mold the combined product into

“cigars,” “tootsie rolls” or “vienna sausages.” The Indictment charges that the defendants knew that such a combination had never been studied in a clinical trial and had never been presented to or approved by the FDA. It is alleged that the reason the defendants promoted the OP-1 products in a mixture with Calstrux was because without a mixing agent, the OP-1 products were at a competitive disadvantage with other legal products. The Indictment also alleges that serious medical problems arose in a number of patients from this untested mix of products.

The Indictment also charges that defendants **STRYKER BIOTECH, LLC** and **MARK PHILIP** made false statements to the FDA about the number of patients that **STRYKER BIOTECH** was treating on an annual basis with OP-1 Putty.

If convicted of the wire fraud, conspiracy, misbranding or false statements charges, **STRYKER BIOTECH** faces fines of the greater of \$500,000 or twice the gross gain or loss from the offense, on each count.

If convicted on the wire fraud charges, **MARK PHILIP, WILLIAM HEPPNER, DAVID ARD** and **JEFF WHITAKER** each face up to 20 years imprisonment, to be followed by 3 years of supervised release and a fine of the greater of \$250,000 or twice the gross gain or loss from the offense, on each count. If convicted on the conspiracy charges, **MARK PHILIP, WILLIAM HEPPNER, DAVID ARD** and **JEFF WHITAKER** each face up to 5 years imprisonment, to be followed by 3 years of supervised release and fine of the greater of \$250,000 or twice the gross gain or loss from the offense, on each count.

If convicted on the misbranding charges, **DAVID ARD** and **JEFF WHITAKER** each face up to 3 years imprisonment, to be followed by 1 year of supervised release and fine of the greater of \$250,000 or twice the gross gain or loss from the offense on each charge. If convicted on the false statement charge, **MARK PHILIP** faces up to 5 years imprisonment, to be followed by 3 years supervised release and fine of the greater of \$250,000 or twice the gross gain or loss from the offense.

The case was investigated by the Food & Drug Administration - Office of Criminal Investigations, the Department of Health and Human Services - Office of Inspector General and the Federal Bureau of Investigation. It is being prosecuted by Assistant U.S. Attorney Jeremy Sternberg of Loucks' Health Care Fraud Unit.

The details contained in the Indictment are allegations. The defendants are presumed to be innocent unless and until proven guilty beyond a reasonable doubt in a court of law.

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